CDC and Marshfield Clinic Vaccine Effectiveness Study;
Study Results Published in MMWR April 18, 2008

TALKING POINTS FOR USE IN ANSWERING QUESTIONS

- Since 2004, CDC and the Marshfield Clinic Research Foundation have been involved in an ongoing influenza vaccine effectiveness study, entitled "**Rapid Analysis of Influenza Vaccine Effectiveness.**"
- The study's goal was to develop a system that can provide interim and final estimates of the influenza vaccine's effectiveness (VE) in preventing laboratory-confirmed influenza infection in a more timely manner than previously available.
- These interim results are from data collected from January 21 through February 8, 2008. However, study enrollment continued until March 28, 2008 and final vaccine effectiveness estimates from this study will cover the period from January 21 through March 28.
- The interim results (January 21-February 8, 2008 data) are being published in an article entitled **"Interim Within Season Estimate of the Effectiveness of Trivalent Inactivated Influenza Vaccine — Marshfield, Wisconsin, 2007–08 Influenza Season"** in the April 18, 2008 issue of CDC's *Morbidity and Mortality Weekly Report* (*MMWR*).
- The MMWR article summarizes initial vaccine effectiveness (VE) results for the trivalent inactivated vaccine (flu shot) in preventing medically attended, laboratory-confirmed influenza among patients living in a 14 zip-code area surrounding Marshfield, Wisconsin during the 2007-08 season.
- The study found overall VE of 58% against circulating influenza A viruses. All influenza A viruses identified were influenza A (H3N2) viruses related to, but drifted from, the H3N2 strain contained in the vaccine.
- No vaccine benefit against influenza B viruses was found. Most influenza B viruses circulating in the U.S. this year are in a different lineage than the B virus strain included in the 2007-2008 vaccine. (Only 20 B viruses were isolated from samples collected from Marshfield study participants through February 8.)
- No influenza A (H1N1) viruses were identified and, thus, no VE estimate is available for H1N1.
- While the VE against the A (H3N2) viruses is less than might be expected during a season when the viruses in the vaccine and circulating viruses are well matched, these interim results suggest that **vaccination provided substantial protection against H3N2 influenza-associated medically attended illness in the study population.** (During well-matched years, clinical trials have shown VE between 70% and 90% for inactivated influenza vaccines in the prevention of serologically confirmed influenza infection.)
- **The 58% VE against drifted H3N2 viruses supports past studies indicating that vaccination can provide cross-protection against different, but related viruses.**

- Overall VE was 44% in this study when all influenza cases were combined, but the mix of influenza A (H1N1), influenza A (H3N2) and B viruses that circulated in this study population may be different from the mix of A and B viruses in other regions and thus the overall VE would also vary.
- According to the interim study results, people who were vaccinated, who later became ill with fever, chills or cough that lead them to seek medical care, were 44% less likely to have the flu (diagnosed by PCR) than unvaccinated people who became ill with fever, chills and cough that lead them to seek medical care.
- **The measurable benefit demonstrated in this study supports existing public health practice of continuing to recommend influenza vaccination even when there is indication of a suboptimal antigenic match between vaccine viruses and circulating influenza viruses.**
- Influenza A (H3N2), influenza A (H1N1) and influenza B viruses have co-circulated in the US this year.
- Influenza A (H3N2) viruses have predominated in seven of nine U.S. regions this season overall and influenza A (H1N1) viruses have predominated in the other two regions (Pacific and Mountain).
- Data from CDC's most recent *FluView* weekly influenza surveillance report (the week ending April 5) indicate that while influenza activity has declined in the United States since mid-February, influenza viruses are continuing to circulate this season (13.2% of viruses tested during the week ending April 5 were positive for influenza).
- While influenza A (H3N2) viruses were the predominant virus in the U.S. this season, the majority of **recently** isolated viruses are influenza B viruses; the virus for which no measurable protection from the vaccine was observed in this study.
- Since influenza viruses can circulate into May, the study results can be used by clinicians during the remainder of the season to anticipate vaccine failures in patients exposed to influenza B.
- Antiviral medications oseltamivir and zanamivir both can be used for the treatment and for the prevention of influenza B and influenza A. For more information on influenza antiviral medication use, see http://www.cdc.gov/flu/protect/antiviral/index.htm.

Notes on Marshfield Clinic Vaccine Effectiveness Data

- Different influenza viruses can circulate in different parts of the country at different times so data collected from Marshfield Clinic in Wisconsin may not be nationally representative in terms of influenza activity or vaccine effectiveness.
- In addition, the mix of circulating influenza strains may also change within a single influenza season among Marshfield Clinic patients. Thus, influenza vaccine effectiveness estimates may vary over the course of the season and across strains. For this reason,the final VE results from this study may change somewhat from the interim results published in the week's MMWR.

- Marshfield analyzes vaccine effectiveness in relation to one outcome: influenza-related medically attended outpatient illness.
- CDC is not able to measure the effects of the vaccine in preventing influenza complications (such as influenza-related hospitalizations) with the vaccine effectiveness data available now from the Marshfield Clinic.

Background on Marshfield Clinic

The Marshfield Clinic is a private medical group in Wisconsin, consisting of 774 physicians in more than 40 centers throughout northern, central and western Wisconsin. Its research division, Marshfield Clinic Research Foundation (MCRF), was established in 1959 and conducts a wide-range of medical research activities. Marshfield Clinic has an electronic medical database, which maintains uniform data, including information on influenza vaccination, for all patients,

Other Surveillance Systems that Determine Vaccine Effectiveness

CDC has other surveillance systems for estimating vaccine effectiveness. These systems cover multiple sites across the country, which provides vaccine effectiveness data on different populations in areas where different influenza strains may predominate. However, these systems produce their estimates after each flu season has ended.